

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF TEXAS  
MARSHALL DIVISION**

ERFINDERGEMEINSCHAFT UROPEP  
GbR,

*Plaintiff,*

V.

ELI LILLY AND COMPANY,

*Defendant.*

Case No. 2:15-CV-1202-WCB

## **MEMORANDUM OPINION AND ORDER**

Before the Court is Plaintiff UroPep’s Motion to Preclude Lilly’s Experts from Presenting Testimony that Contradicts the Court’s Summary Judgment Ruling (“Motion to Preclude”), Dkt. No. 257. The motion is GRANTED IN PART and DENIED IN PART.

UroPep's motion is directed to barring some or all of the testimony corresponding to seven expert reports submitted by Lilly. UroPep explains that its motion is directed to three categories of what it considers impermissible opinion testimony.

First, UroPep objects to any testimony from Lilly’s experts on indefiniteness and non-infringement issues that contradict this Court’s claim constructions and its March 3, 2017, summary judgment order, Dkt. No. 234. Relatedly, UroPep objects to any expert testimony to the effect that tadalafil is not 20 times more selective for PDE5 than for PDE11. UroPep argues that any such testimony would be inconsistent with this Court’s March 3 order, in which the Court held that the ’124 patent only requires selectivity for PDE5 as compared to PDE1 through PDE4.

Second, UroPep objects to testimony from one of Lilly's experts, Dr. Joseph A. Beavo, regarding three prior art compounds that Lilly claims are PDE5 inhibitors. UroPep argues that

the three compounds are not selective inhibitors, within the meaning of the Court's definition of that term for purposes of UroPep's U.S. Patent No. 8,791,124 ("the '124 patent"). For that reason, UroPep argues, evidence regarding those compounds is irrelevant and should be excluded.

Lilly responds that it has no intention of introducing evidence that would contradict the Court's claim construction. In particular, Lilly represents that it will not offer expert testimony or opinion that Lilly does not infringe the '124 patent because tadalafil treats only the signs and symptoms of BPH and does not treat enlargement of the prostate. Defendant Eli Lilly & Company's Opposition to Plaintiff Erfindergemeinschaft UroPep GbR's Motion to Strike Experts ("Lilly's Response"), Dkt. No. 263, at 1-2.

In addition, Lilly represents that it will not offer any expert testimony or opinion that Lilly does not infringe the '124 patent because Cialis is not 20 times as selective for PDE5 as it is for PDE6 through PDE11. However, Lilly states that it intends to offer expert testimony going to the issues of written description and enablement, as set forth in portions of Lilly's experts' reports that UroPep is seeking to exclude. Lilly's Response, Dkt. No. 263, at 2-3. The parties have therefore joined issue in that regard.

With respect to the three compounds as to which Dr. Beavo intends to offer expert testimony corresponding to the contents of his second report, Lilly argues that Dr. Beavo's testimony regarding those compounds is relevant and does not controvert anything in the Court's March 3, 2017, order.

Finally, in its opposition and in the Joint Proposed Pre-trial Order, Dkt. No. 251, Lilly has requested direction from the Court as to the status of the Court's indefiniteness ruling in the

March 3, 2017, summary judgment order, so that the parties will understand what the Court's intentions are with regard to the indefiniteness issue.

### **I. Expert Testimony That Would Contradict the Court's March 3 Order**

Because Lilly has made clear that it does not intend to elicit expert testimony that would contradict any of the Court's claim constructions, the only remaining question raised by UroPep's first and second objections is whether Lilly's expert testimony will conflict with anything in the portion of the Court's March 3, 2017, order dealing with indefiniteness. To resolve that issue, it is necessary to address both the Court's role in deciding the indefiniteness issue and Lilly's constitutional right to a jury trial on other issues that may be related to the matters resolved by the Court in the course of its indefiniteness discussion.

Lilly intends to have its experts testify that the '124 patent gives inadequate guidance as to whether a particular compound is a PDE5 inhibitor. On the assumption that the indefiniteness issue has been resolved by the Court or, in any event, is an issue of law for the Court and not for the jury, Lilly proposes to offer that evidence not on the issue of indefiniteness, but instead in support of Lilly's written description and enablement defenses. UroPep has two responses: first, that some of the testimony in question was expressly directed to the issue of indefiniteness and cannot be repurposed as relevant evidence going to written description and enablement; and second, that much of the expert testimony that is expressly directed to written description and enablement conflicts with the Court's March 3, 2017, indefiniteness ruling and thus should be barred at trial.

The first issue raised by the parties' briefs relates to the status of the indefiniteness issue in this case. The Court held a claim construction hearing on June 23, 2016. The docket control order that was in effect at that time, like each of the subsequent docket control orders issued in

this case, advised that “the parties are directed to include any arguments related to the issue of indefiniteness in their Markman briefing.”

In its initial claim construction briefing, Lilly argued that the claim term “inhibitor of phosphodiesterase (PDE) V” should be construed as a “means plus function” term under 35 U.S.C. § 112, ¶ 6. If viewed in that manner, Lilly argued, the claims of the ’124 patent would be limited to two compounds, zaprinast and MY5445. In the alternative, Lilly argued that the term “inhibitor of phosphodiesterase (PDE) V” should be construed broadly to mean “any compound able to inhibit PDE V.” At that time, Lilly reserved the right to call expert witnesses regarding claim construction, see Dkt. No. 84, at 6, but Lilly did not call any witnesses at the claim construction hearing, which was held on June 23, 2016.

On August 11, 2016, the Court entered its claim construction order. Dkt. No. 131. In that order, the Court construed several of the terms in dispute. However, the Court postponed construing the phrase “inhibitor of phosphodiesterase (PDE) V” pending the Court’s ruling on Lilly’s motions for summary judgment of noninfringement, Dkt. No. 119, and invalidity, Dkt. No. 120. Lilly’s invalidity motion was based on the alleged failure of the ’124 patent to satisfy the written description requirement of 35 U.S.C. § 112, ¶ 1. On October 21, 2016, the Court entered an order that denied Lilly’s motions for summary judgment. In that order, the Court construed the term “inhibitor of phosphodiesterase (PDE) V.” Dkt. No. 149. The Court rejected Lilly’s argument that the term should be construed as a means-plus-function limitation, and the Court construed the term to mean “a compound that selectively inhibits PDE V.” Id. at 27.

Lilly subsequently filed a motion for summary judgment on indefiniteness. In the course of the briefing of that and other related motions, it became clear that the parties disagreed about the meaning of the Court’s claim construction. Accordingly, in an order entered on March 3,

2017, the Court clarified its claim construction, construing the term “selectively inhibits” in its earlier claim construction to mean a compound that is at least 20 times more effective in inhibiting PDE5 compared to PDE1 through PDE5. Dkt. No. 234. The Court then turned to Lilly’s motion for summary judgment of indefiniteness. The Court first noted that indefiniteness is a question of law for the Court and that the general principles of claim construction apply to the question of indefiniteness. Dkt. No. 234, at 28-29. The Court then ruled that in light of the manner in which the claim construction issue had been litigated, Lilly had not waived its indefiniteness argument by not raising it earlier in the proceedings. Id. at 30-33. The Court also rejected UroPep’s argument that Lilly had waived its indefiniteness argument by submitting much of its evidence on that issue belatedly, through a responsive report of its expert, Dr. David Rotella.

On the merits of the indefiniteness issue, the Court held that Lilly had failed to show that the ’124 patent claims were invalid for indefiniteness. Dkt. No. 234, at 34-47. After reviewing all of the argument and evidence presented by the parties on the indefiniteness issue, the Court stated that “the asserted claims are . . . sufficiently definite to satisfy the requirements of section 112, paragraph 2, of the Patent Act,” id. at 44, and that “[t]he Court holds that the claims of the ’124 patent are not invalid for indefiniteness,” id. at 47.

In its response to UroPep’s Motion to Preclude, Dkt. No. 263, and also in the Proposed Joint Pretrial Order, Dkt. No. 251, Lilly sought the Court’s guidance as to whether the indefiniteness issue is still in this case, given that the Court’s March 3, 2017, order had been issued in response to Lilly’s motion styled as a motion for summary judgment.

The Court now advises the parties that the issue of indefiniteness has been resolved. The Court’s March 3, 2017, order held that the claim language, as construed by the Court, is

“sufficiently definite to satisfy the requirements of section 112, paragraph 2, of the Patent Act,” and that “the claims of the ’124 patent are not invalid for indefiniteness.” Even though Lilly addressed the issue of indefiniteness in a paper denominated as a motion for summary judgment, the indefiniteness issue was before the Court as a part of the Court’s claim construction, and it was properly addressed and finally resolved in conjunction with the claim construction process. That conclusion follows from the principles the Federal Circuit has announced regarding the role of the indefiniteness inquiry in infringement litigation.

First, the Federal Circuit has made clear that indefiniteness is a question of law for the court. Ethicon Endo-Surgery, Inc. v. Covidien, Inc., 796 F.3d 1312, 1317 (Fed. Cir. 2015); Hoffer v. Microsoft Corp., 405 F.3d 1326, 1328 (Fed. Cir. 2005); Intellectual Prop. Dev., Inc. v. UA-Columbia Cablevision of Westchester, Inc., 336 F.3d 1308, 1318 (Fed. Cir. 2003). Moreover, the general principles of claim construction apply to the question of indefiniteness. Eli Lilly & Co. v. Teva Parenteral Meds., Inc., 845 F.3d 1357, 1370 (Fed. Cir. 2017); Eon Corp. IP Holdings LLC v. AT&T Mobility LLC, 785 F.3d 616, 620 (Fed. Cir. 2015); Biosig Instruments, Inc. v. Nautilus, Inc., 783 F.3d 1374, 1377-78 (Fed. Cir. 2015); Praxair, Inc. v. ATMI, Inc., 543 F.3d 1306, 1319 (Fed. Cir. 2008) (“Indefiniteness is a matter of claim construction, and the same principles that generally govern claim construction are applicable to determine whether allegedly indefinite language is subject to construction.”). In fact, as the Federal Circuit has explained, indefiniteness presents a question of law that is “inextricably intertwined with claim construction,” Cox Commc’ns, Inc. v. Sprint Commc’n Co. LP, 838 F.3d 1224, 1232 (Fed. Cir. 2016) (quoting Atmel Corp. v. Info Storage Devices, Inc., 198 F.3d 1374, 1379 (Fed. Cir. 1999)); see also Personalized Media Commc’ns, LLC v. Int’l Trade Comm’n, 161 F.3d 696, 705 (Fed. Cir. 1998) (indefiniteness “is a legal conclusion that is drawn from the

court’s performance of its duty as the construer of patent claims”); ePlus, Inc. v. Lawson Software, Inc., 700 F.3d 509, 517 (Fed. Cir. 2012) (same). As such, the issue of indefiniteness does not ordinarily turn on an underlying factual dispute that is not amenable to decision on summary judgment. See Exxon Res. & Eng’g Co v. United States, 265 F.3d 1371, 1376 (Fed. Cir. 2001), and cases cited therein. As in the case of claim construction, factual issues relating to indefiniteness determinations can arise; when factual findings are required to be made, however, those findings are made by the court and reviewed for clear error. See Media Rights Techs, Inc. v. Capital One Fin. Corp., 800 F.3d 1366, 1371 (Fed. Cir. 2015); Teva Pharm. USA, Inc. v. Sandoz, Inc., 789 F.3d 1335, 1341-42 (Fed. Cir. 2015).

Lilly expresses uncertainty about whether this Court has finally ruled on the issue of indefiniteness. Citing Meadwestvaco Corp. v. Rexam Beauty & Closures, Inc., 731 F.3d 1258 (Fed. Cir. 2013), and Lisle Corp. v. A.J. Mfg. Co., 398 F.3d 1306, 1317 (Fed. Cir. 2005), Lilly explains that it wants to take whatever measures are necessary to ensure that it not be found to have waived its indefiniteness argument for purposes of appeal, even though it will not be offering evidence on that issue to the jury at trial. In the Court’s view, Lilly has plainly not waived its right to appeal the Court’s determination on indefiniteness. To be clear, Lilly is not required to offer evidence going to indefiniteness at trial, and will not be allowed to do so. Lilly asks whether this Court in its March 3, 2017, order finally ruled on the indefiniteness issue, as opposed to simply having denied Lilly’s motion for summary judgment on that issue. In fact, the Court did both. As the Court stated in its March 3, 2017, order, the Court not only denied summary judgment to Lilly, but also held that the claims of the ’124 patent “are not invalid for indefiniteness.”

In the Meadwestvaco case, the district court did not make clear whether it was merely denying summary judgment or ruling on the merits of the indefiniteness issue. Under those circumstances, the Federal Circuit found that there had been a waiver because the defendant had not raised the indefiniteness issue at the subsequent bench trial. In this case, Lilly has made its intentions clear—that it has no intention of abandoning its indefiniteness claim—and the Court views that as fully sufficient to preserve that issue for appeal. Moreover, in this case, unlike in Meadwestvaco, this Court has sought to make its intentions clear—that the Court’s ruling on the summary judgment motion was “the last word on the matter until appeal.” ePlus, Inc., 700 F.3d at 517-18.<sup>1</sup>

While the Court’s ruling on the indefiniteness issue is final, that does not resolve the question of whether the Court’s ruling—and the Court’s component findings made in the course of its analysis of the indefiniteness issue—should be accorded binding effect for other purposes at trial, as UroPep argues. The problem is this: To the extent the Court’s findings are given preclusive effect when similar factual questions arise in connection with other legal issues at trial, any such preclusion could have the effect of restricting Lilly’s Seventh Amendment right to have the jury decide the factual issues in the case without the constraint of a Court’s order resolving factual issues that the jury would otherwise be charged with deciding.

This issue is closely akin to the issue addressed by the Supreme Court in two seminal Seventh Amendment cases, Dairy Queen v. Wood, 369 U.S. 489 (1962), and Beacon Theatres, Inc. v. Westover, 359 U.S. 500 (1959). Those cases stand for the proposition that a district court’s decision on an issue cannot, consistent with the Seventh Amendment, be binding on a

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<sup>1</sup> UroPep has objected to several of Lilly’s proposed trial exhibits on the ground that the exhibits were offered in support of Lilly’s indefiniteness case, an issue that the Court has already decided. See Dkt. No. 268, at 5-6, 14 (objecting to Lilly trial exhibits 1259, 1600, 1601, 1602, 1603, 1604). UroPep’s objection is SUSTAINED.

jury on an issue that is triable to the jury. See Shum v. Intel Corp., 499 F.3d 1272, 1277 (Fed. Cir. 2007); Gardco Mfg., Inc. v. Herst Lighting Co., 820 F.2d 1209, 1212-13 (Fed. Cir. 1987).

In this case, the course that UroPep invites the Court to follow would potentially have the effect of precluding the jury from deciding the issues of written description and enablement free from the fetters of the Court’s pronouncements made in the course of its earlier decision on the indefiniteness defense.

The Court must therefore determine whether the factual findings underlying its indefiniteness ruling are intertwined with factual issues Lilly wishes to present in support of its enablement and written description defenses. In the Court’s indefiniteness ruling, the key factual findings were (1) that the ’124 patent “points to” a detailed testing protocol for determining whether a particular compound qualifies as a PDE5 inhibitor; (2) that any uncertainty in determining whether zaprinast satisfies the 20-fold selectivity test does not, by itself, support the inference that testing of many or all other inhibitors would generate similar uncertainty; and (3) that zaprinast is specifically identified in the patent as a PDE5 inhibitor. Dkt. No. 234, at 35.

UroPep argues that large portions of several of Lilly’s expert reports are contrary to those findings and thus should be precluded from use at trial. That argument fails to recognize, however, that “there is a fundamental difference between *evidence* and *issues*.” Gardco Mfg., Inc. v. Herst Lighting Co., 820 F.2d at 1213. The fact that particular evidence may have been submitted in support of a failed indefiniteness argument does not disable the evidence from being used to mount, for example, a successful enablement defense.

The relevant question is whether Lilly now wishes to relitigate, in support of its written description and enablement defenses, the factual findings that the Court decided in its

indefiniteness ruling. Based on Lilly’s representations, that may not be the case, but the Court has not yet seen the full contours of Lilly’s defenses.

It is difficult to discern in the abstract whether the indefiniteness findings will overlap with the factual issues underlying Lilly’s enablement and written description defenses. But in any event the Court’s earlier factual findings would not necessarily preclude Lilly from offering evidence at trial that is relevant to those defenses, even if the same evidence was previously offered in support of Lilly’s unsuccessful indefiniteness defense.

At this point, the Court is not aware of any facts that Lilly seeks to establish in support of its written description and enablement defenses that contradict one of the Court’s indefiniteness findings. But it is possible that the problem could surface at trial, giving rise to the Seventh Amendment issue discussed above. There are several ways of resolving that conundrum, but the one that seems both most efficient and fully protective of Lilly’s Seventh Amendment rights is for the Court to treat the factual analysis conducted in the course of the Court’s indefiniteness order as non-binding on Lilly for purposes of Lilly’s presentation of its written description and enablement defenses to the jury at trial. See Dairy Queen, 369 U.S. at 479 (if legal claims involve factual issues “common with those upon which [the] claim to equitable relief is based, the legal claims involved in the action must be determined prior to any final court determination of [the] equitable claims.”); accord Shum, 499 F.3d at 1277. That resolution will preserve Lilly’s Seventh Amendment right to present its defenses without the constraints imposed by the Court’s previous rulings made in connection with the indefiniteness ruling. At the same time, that procedure will respect the Court’s authority to decide the indefiniteness issue as a legal matter in conjunction with the claim construction process. And it will not have the effect of making the finality of the resolution of the indefiniteness issue turn on whether a party later

wishes to raise an issue at trial that overlaps with some determination made in the course of the indefiniteness proceedings.<sup>2</sup>

Accordingly, the Court will DENY UroPep's Motion to Preclude insofar as it seeks to bar testimony from Lilly's experts that is inconsistent with some aspect of the Court's indefiniteness analysis set forth in the Court's March 3, 2017, order. As indicated above, of course, Lilly will not be permitted to introduce evidence that is contrary to the Court's claim construction. To that extent only, the Court will GRANT UroPep's Motion to Preclude.

## **II. Testimony from Dr. Beavo Concerning Three Prior Art Compounds**

In their respective briefs, the parties touch on the question whether Dr. Beavo should be permitted to testify in accordance with his second report, which concerns compounds known as flavoxate, MFCA, and Permixon, three compounds that are alleged to be PDE5 inhibitors. Those compounds are not alleged to be invalidating prior art, but Lilly seeks to introduce evidence regarding those compounds as relevant to written description, enablement, and damages. The relevance of the evidence to damages, according to Lilly, is that it shows the existence and availability of noninfringing, PDE5-inhibiting alternatives to tadalafil.

Based on the limited presentation made by the parties in their motions and at the pretrial conference, the Court is not persuaded that Dr. Beavo should be barred from testifying about the

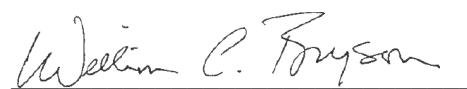
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<sup>2</sup> There are other ways the Court could achieve the same objective, and the Federal Circuit has recognized that district courts enjoy some flexibility in the way that they implement the policies underlying the Dairy Queen and Beacon Theatres cases. See In re Glaxo, Inc., 69 F.3d 553, 1995 WL 616605(Fed. Cir. Oct. 6, 1995) (table). For example, the Court could vacate its indefiniteness ruling, subject to reissuing it following the trial, if necessary. That procedure would avoid the preclusive effect of the indefiniteness ruling, but without conferring any benefit beyond that conferred by the process adopted by the Court in this case. Alternatively, and more generally, courts could postpone ruling on indefiniteness challenges until after trial. But that procedure could be cumbersome and would deny the parties the benefits of early resolution of an important and potentially dispositive issue. The Court is satisfied that the procedure to be employed here is the most efficient, at least in the specific context of this case.

three compounds at trial. UroPep's motion to preclude his testimony on that subject is therefore DENIED.

IT IS SO ORDERED.

SIGNED this 13th day of April, 2017.

  
William C. Bryson  
WILLIAM C. BRYSON  
UNITED STATES CIRCUIT JUDGE